REMARKS

In the Office Action dated May 7, 2008, the Examiner has set forth a requirement for restriction under 35 U.S.C. §121, alleging that the subject matter defined by the claims of the present invention represents the following three separate and distinct inventions:

Group I.	Claims 1, 2 and 4-28, drawn to method of characterizing and isolating a population of cells, classified in class 435, subclass 7.23, for example.
Group II.	Claims 3-28, drawn to method of diagnosing a disease state, classified in class 436, subclass 811, for example.
Group III.	Claim 29, drawn to a product, i.e., population of isolated cells, classified in class 435, subclass 372, for example.

The Examiner also requires Applicants to elect one of the dendritic cell immunogens in Claims 9-21 and one of the non-dendritic cell immunogens in Claims 23-28 for further examination.

In order to be fully responsive to the Examiner's requirement for restriction, Applicants provisionally elect to prosecute the subject matter of Group I, Claims 1, 2 and 4-28, drawn to methods of characterizing and isolating a population of cells. Applicants also elect CD45 as the dendritic cell immunogen species and CD34 as the non-dendritic cell immunogen species for examination. Presently, within Group I, claims 1, 2, 4-8 and 22-28 are generic relative to the elected dendritic cell immunogen CD45, and claim 1 also recites CD45 specifically. Claims 1, 2, 4-17 and 19-22 are generic relative to the elected non-dendritic cell immunogen CD34, and claims 22 and 28 recite specifically CD34. Applicants reserve the right to file one or more divisional applications directed to the non-elected subject matter in this application in the event that the pending restriction requirement is made final.

In addition, Applicants have amended Claim 1 to incorporate the subject matter of Claim 18 and have canceled Claim 18, without prejudice. Support for the amendment to Claim 1 is found in originally filed Claims 1 and 18. No new matter is introduced by the amendment to Claim 1.

However, pursuant to 37 C.F.R. §§ 1.111 and 1.143, Applicants hereby traverse the Examiner's requirement for restriction and request reconsideration thereof in view of the following remarks.

An Examiner's authority to require restriction is defined and limited by statute:

> If two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions.

35 U.S.C. § 121, first sentence (emphasis added). The implementing regulations of the Patent and Trademark Office include the mandate that restriction is appropriate only in cases presenting inventions which are both independent and distinct, 37 C.F.R. §§1.141-142. Without a showing of independence and distinctness, a restriction requirement is unauthorized. In the present application, the claims which the Examiner has grouped separately are not "independent and distinct" so as to justify the restriction requirement.

In the first instance, Examiner has asserted that Groups I and II are patentably distinct inventions because Groups I and II are not disclosed as capable of use together. The Examiner alleges that Group I characterizes and isolates a population of dendritic cells from a patient sample based on cell surface antigen expression using immunoreactive molecules; and Group II is a diagnostic method whereupon number and type of subclasses of dendritic cells are determined using immunoreactive molecules to provide an indication of a disease state.

The Examiner acknowledges that Groups I and III are related as process of making and product made. However, the Examiner alleges that the leucocyte dendritic cell population in Group I can be characterized and isolated using gel microdrop technology. The Examiner acknowledges that Groups II and III are related as process of making and product made. However, the Examiner alleges that the leucocyte dendritic cell population in Group III can be used as control sample in cell-based immunological assays.

Applicants respectfully submit that the present invention is directed to methods of characterizing dendritic cells by employing immunointeractive molecules directed to dendritic cell immunogens and non-dendritic cell immunogens. Groups I-III are simply different aspects of the present invention.

Specifically, Applicants respectfully submit that Group I and Group II are related. The diagnostic method of Group II employs the result of cell characterization method of Group I in determination of a disease state. Thus, Groups I and II are not independent.

Moreover, Applicants respectfully submit that Groups I and Group III, and Groups II and III, are related, respectively, as acknowledged by the Examiner. Applicants further respectfully submit that the methods of Group I and II merely teach how to isolate and use the leucocyte dendritic cell population of Group III. Accordingly, Groups I and III as well as Groups II and III are all related and not independent.

Applicants respectfully submit that Groups I-III are all different aspects of a single invention. The courts have recognized that it is in the public interest to permit applicants to claim several aspects of their invention together in one application, as the applicants have done herein. The CCPA has observed:

> We believe the constitutional purpose of the patent system is promoted by encouraging applicants to claim, and therefore to describe in the manner required by 35 U.S.C. §112 all aspects as to what they regard as their invention, regardless of the number of statutory classes involved.

In re Kuehl, 456 F.2d 658, 666, 117 U.S.P.Q. 250, 256 (CCPA 1973). This interest is consistent with the practical reality that a sufficiently detailed disclosure supporting claims to one aspect of an invention customarily is sufficient to support claims in the same application to other aspects of the invention.

The Examiner also states that the inventions have acquired a separate status in the art as evidenced by the separate classification and recognized divergent subject matter and would require independent searches. Thus, the Examiner concludes that restriction for examination purposes is proper.

Reliance on the supposed classification of the groups of claims does not establish independence and distinctness. The classification system has no statutory recognition as evidence of whether inventions are independent and distinct. The classification system is instead an aid in finding and searching for patents.

The classification system is also an unreliable basis for requiring restriction between claims to the various aspects of applicants' unitary invention, because the system exhibits considerable overlap in technical definitions. In particular, the definitions of classes and subclasses in the classification system do not prevent the Examiner from basing patentability decisions, as to claims assigned to one group, on patent references found in the classes or subclass(es) with which he associated another group of claims.

Furthermore, the classification system is a poor basis for requiring restriction between related aspects of an invention because classifications and definitions change over time. Thus, a

classification that might have seemed to support restriction at a given time could change, thereby casting a shadow over the propriety of the restriction requirement later on during the term of the patents issuing from parent and divisional applications. Indeed, classifications seem largely to change in response to considerations of administrative convenience, and often in response to nothing more than growth in the number of patents in a given class or subclass. These considerations have nothing to do with whether the subject matter of patents assigned to different classifications is "independent and distinct" as those terms are used in 35 U.S.C. §121, which fact proves that basing restriction requirements on the classification system is improper.

Applicants respectfully suggest that in view of the continued increase of official fees and the potential limitation of an applicant's financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts. Moreover, under the regulatory changes as a consequence of the General Agreement on Trade and Tariffs (GATT), applicants are required to conduct simultaneous prosecution, as here, requiring excessive filing costs or to otherwise compromise the term of related patent assets.

It is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting. The third sentence of 35 U.S.C. §121, which states that a patent issuing on a parent application "shall not be used as a reference" against a divisional application or a patent issued thereon, does not provide comfort to applicants against such allegations. The Court of Appeals for the Federal Circuit has declined to hold that § 121 protects a patentee from an allegation of same-invention double patenting, Studiengesellschaft Kohle

GmbH v. Northern Petrochemical Co., 784 F.2d 351, 355, 288 U.S.P.Q. 837, 840 (Fed. Cir. 1986). In Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 16 U.S.P.Q. 2d 1436 (Fed. Cir. 1990), the court held that §121 does not insulate a patentee from an allegation of "obviousness-type" double patenting, and in fact affirmed the invalidation on double patenting grounds of a patent that had issued from a divisional application filed following a restriction requirement. Furthermore, it is far from clear that the step of filing a terminal disclaimer is available to resolve a double patenting issue that arises after the issuance of a patent on the divisional application.

All these considerations indicate that the imposition of a restriction requirement with inadequate authority can lead to situations in which an applicant's legitimate patent rights are exposed to uncertainty and even extinguished. Accordingly, to protect a patentee's rights and to serve the public interest in the legitimacy of issued patents, Applicants respectfully urge the Examiner not to require restriction in cases such as the present application wherein various aspects in a unitary invention are claimed.

Finally, Applicants respectfully submit that a determination to make the pending restriction requirement final must evidence the patentable distinctness of all defined three groups, one from the other, as presented by the Examiner.

In view of the foregoing comments, it is respectfully urged that the Examiner reconsider and withdraw the requirement for restriction and provide an action on the merits with respect to all the claims.

Respectfully submitted,

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